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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Shiguang Yu

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EXAMINER

CHOI, FRANK I

ART UNIT

PAPER NUMBER

1616

MAIL DATE

DELIVERY MODE

11/16/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.		Applicant(s)	
	09/683,003		YU ET AL.	
	Examiner		Art Unit	
	Frank I. Choi		1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,6 and 7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2,6 and 7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2,6,7 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while enabling for treatment of poor hair growth or alopecia where the cause is selenium toxicity or hypothyroidism, does not reasonably provide treatment of poor hair growth or alopecia over the entire scope of the claim where the dog or cat is receiving a properly nutritious diet. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The nature of the invention:

The claims are directed to control of the rate of hair growth in dog or cat in need thereof and which receive a properly nutritious diet with about 0.1 to about 4.5 mg/kg of the diet on a dry matter basis.

The state of the prior art and the predictability or lack thereof in the art:

The prior art of record discloses that dietary supplementation of selenium in can increase wool production in sheep, that selenium toxicity in dogs, cats and sheep can result in hair loss or alopecia and that selenium should be provided in or reduced to levels which do not result in toxicity. The prior art of record also discloses that hypothyroidism can result in poor hair growth or alopecia and that selenium supplementation is effective in treating hypothyroidism. As such, predictability in the art is low with respect to treatment of poor hair growth or alopecia other than

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in wool production of sheep, selenium toxicity or hypothyroidism resulting from selenium deficiency.

The amount of direction or guidance present and the presence or absence of working examples:

The Specification provides one example in which hair is shaved from different areas on dogs and the rate of hair growth is measured over time in relation to the amount of selenium (provided as selenomethionine) provided in a diet which is nutritionally balanced and complete for an adult dog except for selenium (Specification, paragraphs 0010-0015). As such, the hair and hair follicle is still present. Alopecia, on the other hand, is the absence or loss of hair. See Stedman's Medical Dictionary (27th ed. 2000) (printed from <http://www.thomsonhc.com/pdrel/librarian/PFDefaultActionId/pdrcommon.Stedmans> on 11/2/2006). Since the example does not show that selenium administration result in new hair growth, the example does not provide evidence that administration of selenium will treat alopecia. The test showed hair growth of cut hair at each amount tested although at certain amounts (0.034, 0.085, 5.045 mg/kg dietary Se) there was decreased hair growth at week 11 and week 22 compared to other amounts (0.123, 0.527, 1.025 mg/kg dietary Se (Paragraph 0015, Table 1). In an article in which the inventors were the named authors, the article indicated that the daily hair growth for beagle dogs is 0.34-0.40 mm (Yu et al., Page 150). This is higher than any of the daily hair growth rate data set forth in Table 1 of the Specification. As such, the only example provided actually provides evidence the claimed range is not effective to treat poor hair growth or alopecia in all animals, especially dogs. Further, the working example did not provide a diet that was properly nutritious diet if "properly nutritious diet" is defined to mean that the dog or cat was given a diet that met the

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selenium requirements of the dog or cat. The diet in the working example was deficient in selenium and had to be supplemented with selenium where needed.

The breadth of the claims and the quantity of experimentation needed:

The claims are broad in that they claim treatment poor hair growth or alopecia without limitation as to the cause of the poor hair growth or alopecia. Further, no base line is provided for what would constitute poor hair growth in dogs or cats. The evidence submitted and the prior art of record does not provide evidence that is commensurate in scope with the claimed invention. The example in the Specification sets forth hair growth rates in beagles in amounts falling within the claimed range of selenium that are below the daily hair growth rate in beagles and the diet used was deficient in selenium and had to be supplemented with selenium. The prior art discloses or suggests providing amounts of dietary selenium in or reducing amounts of dietary selenium to levels which are not toxic as selenium toxicity can cause poor hair growth or alopecia. The prior art discloses that selenium supplementation can treat hypothyroidism and that hypothyroidism can cause poor hair growth or alopecia. However, the prior art does not disclose that dietary selenium at the levels claimed is generally effective in treating poor hair growth or alopecia what ever the cause and in dogs and cats. As such, it appears that one of ordinary skill in the art would be required to do undue experimentation in order to determine that administration of selenium in a "properly nutritious diet" would be effective in treating poor hair growth or alopecia in a cats and dogs or was not otherwise the result of selenium toxicity or hypothyroidism which is treatable by selenium supplementation.

The Examiner has duly considered the Applicant's arguments but deems them unpersuasive.

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The scope of enablement rejection was not limited to prevention but also to the treatment methods indicated above. Since the Applicant did not address the same the rejection is maintained.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Van Vleet.

Van Vleet expressly discloses supplementing the diet of dogs that was deficient in vitamin E and selenium with 0.5 ppm Se and 1.0 ppm Se as sodium selenite (Pages 769, 770).

Claim 2 is directed to a method for controlling the rate of hair growth in a dog, cat or sheep comprising feeding the dog, cat or sheep from about 0.5 to about 4.5 mg of selenium per kg of diet on a dry matter basis. The term “controlling” encompasses reducing, maintaining or increasing the rate of hair growth. Since the claim does not indicate whether the rate of hair growth is reduced, maintained or increased, the prior art process inherently reads on the claimed method as the amounts administered to the dogs fall within the claimed range of selenium of claim 2.

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The examiner has duly considered the Applicant's arguments but deems them unpersuasive.

The Applicant does not define "properly nutritious diet". Further, in the working example, the dogs were fed a diet which was deficient in selenium. As such, a "properly nutritious diet" as used in the Specification can have deficiencies.

Claims 2, 6, 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over NAC, Nutrient Requirements of Cats (1986) (hereinafter "NAC-NRC) in view of Dey et al..

NAC-NRC discloses that selenium deficiency in cats has not been observed, although it would appear likely from work with other species that a specific dietary requirement does exist (Pg. 19). It is disclosed that levels of selenium in excess of 5 mg/kg are toxic for many animal species but have not been reported to be toxic to the cat (Pg. 19). It is disclosed that based on the requirement of selenium in other species, a minimum requirement of 100 micrograms Se/kg diet is recommended (Pg. 19).

Dey et al. disclose that known toxic effects of selenium, such brittleness of hair and loss of long hair were observed in several individuals of the four animal species studied, flying squirrel, leopard cat, civit cat and leopard (Pages 1,8).

The prior art discloses feeding of a minimum of 100 microgram Se/kg diet to cats and that selenium levels in excess of 5 mg/kg have been reported to be toxic in other animal species. The difference between the prior art and the claimed invention is that the prior art does not expressly disclose treatment of poor hair growth or alopecia in cats. However, the prior art amply suggests the same as the prior art discloses that a minimum requirement of 100 micrograms Se/kg diet is recommended, that a level in excess of 5 mg/kg of diet has been

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reported to be toxic in other species of animal, and that selenium toxicity in leopards, leopard cats and civet cats has resulted in brittle hair and loss of long hair. As such, it would have been well within the skill of and one of ordinary skill in the art to restrict the amount of selenium in the diet to less than 5 mg/kg of diet to a minimum of 100 micrograms/kg of diet with the expectation that said amount would meet the selenium nutritional requirements of the cat while treating or reducing the risk of poor hair growth or alopecia due to selenium toxicity.

The Applicant has duly considered the Applicant's arguments but deems them unpersuasive.

There is no requirement that there be motivation to combine the references.

The Supreme Court in *KSR International Co. v. Teleflex Inc.*, held the following:

(1) the obviousness analysis need not seek out precise teachings directed to the subject matter of the challenged claim and can take into account the inferences and creative steps that one of ordinary skill in the art would employ;

(2) the obviousness analysis cannot be confined by a formalistic conception of the words teaching, suggestion and motivation, or by overemphasis on the importance of published articles and the explicit content of issued patents;

(3) it is error to look only the problem the patentee was trying to solve-any need or problem known in the filed of endeavor at the time of invention and addressed by the prior art can provide a reason for combining the elements in the manner claimed;

(4) it is error to assume that one of ordinary skill in the art in attempting to solve a problem will be led only to those elements of prior art designed to solve the same problem-common sense teaches that familiar items may have obvious uses beyond their primary purposes,

and in many cases one of ordinary skill in the art will be able to fit the teachings of multiple patents together like pieces of a puzzle (one of ordinary skill in the art is not automaton);

(5) it is error to assume that a patent claim cannot be proved obvious merely by showing that the combination of elements was "obvious to try". KSR International Co. v. Teleflex Inc., 82 USPQ2d 1385, 1396, 1397 (U.S. 2007).

One of ordinary skill in the art is not an automaton. One of ordinary skill in the art would recognize that providing selenium at amounts lower the 5 mg/kg of diet would result in increased hair growth. The prior art discloses that amounts higher than said amount results in hair loss. It is apparent that a condition of no hair is essentially zero hair growth which compared to a condition of hair being present is clearly an increase in the rate of hair growth.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been taught by the teachings of the cited reference.

Claims 2, 6,7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arthur et al in view of Awadeh et al., Ahsan et al., Messenger, Daminet et al., NAC-NRS, NAC, Nutrient Requirements of Dogs (1985) (hereinafter NAC-NRD) and NAC-NRC.

Arthur et al. disclose that selenium deficiency impairs thyroid hormone metabolism by inhibiting the synthesis and activity of the iodothyronine deiodinases that convert thyroxine to the more metabolically active triiodothyronine (T3) (Page 37, Abstract).

Awadeh et al. disclose that selenium supplementation increased T3 levels in cows, guinea pigs and calves and that selenium deficient rats had reduced T3 concentrations in plasma (page 1208).

Ahsan et al. disclose that T3 regulates growth, differentiation and development of various tissues and that hypothyroidism leads to dry, coarse and brittle hairs that become increasingly thinner and that sparse scalp hair, loss of the outer third of eyebrows and diminished body hair are often seen in hypothyroidism (page 179). It is disclosed that administration of T3 stimulates the proliferation and/or metabolism of outer root sheath cells and dermal papilla cells (Page 179, Abstract).

Messenger discloses that thyroxine, which is converted to the active hormone triiodothyronine, increased hair length in rats and hair growth in sheep and badgers (pg. 633).

Damiet et al. disclose that alopecia is a common clinical sign of hypothyroidism (pg. 699).

NAC-NRS disclose feeding a maximum of 2 ppm or mg/kg of diet dry matter of selenium and that chronic selenium toxicity occurs when sheep consume over a prolonged period of time seleniferous plants containing more than 3 ppm of selenium and that signs of said toxicity include loss of wool (Page 22, Page 50, Table 7). It is disclosed that the minimum requirement of selenium in sheep is 0.1-0.2 mg/kg diet dry matter (Page 50, Table 7).

NAC-NRD discloses that dogs fed a purified, Torula yeast-based diet that was deficient in selenium over a period of 40 to 60 days exhibited clinical signs of deficiency whereas dogs fed diets supplemented with 0.5 mg and 1.0 mg/kg selenium did not develop clinical signs of deficiency (page 21). It is disclosed that the required minimum concentration of selenium in dog food formulated for growth is 0.11 mg/kg dry basis (3.67 kcal ME/g) (Page 44, Table 2). It is disclosed that the minimum selenium requirement of dogs for growth and maintenance (amounts per kg of body weight per day (average 30kg BW growing beagle puppy consuming 600 kcal

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ME/day, average 10-kg-BW adult dog consuming 742 kcal ME/day) is 6.0 and 2.2 micrograms, respectively (Page 44, Table 1).

NAC-NRC discloses that selenium deficiency in cats has not been observed, although it would appear likely from work with other species that a specific dietary requirement does exist (Pg. 19). It is disclosed that levels of selenium in excess of 5 mg/kg are toxic for many animal species but have not been reported to be toxic to the cat (Pg. 19). It is disclosed that based on the requirement of selenium in other species, a minimum requirement of 100 micrograms Se/kg diet is recommended (Pg. 19).

The prior art discloses that disclose that selenium deficiency impairs thyroid hormone metabolism by inhibiting the synthesis and activity of the iodothyronine deiodinases, which convert thyroxine to the more metabolically active triiodothyronine (T3). The difference between the prior art and the claimed invention is that the prior art does not expressly disclose a method for controlling the rate of hair growth or treating poor hair growth or alopecia in a dog or cat with about 0.5 to about 4.5 selenium mg/kg. However, the prior art amply suggests the same as the prior art discloses that selenium deficiency impairs thyroid hormone metabolism and conversion to T3, that selenium deficiency results in T3 deficiency, that T3 stimulates hair cell growth and/or metabolism, that administration of thyroxine, which is converted to T3 by an enzyme which requires selenium, is effective in growing hair in rats, sheep and badgers and that alopecia is a symptom of hypothyroidism. The prior art discloses the selenium requirements for dogs, cats and sheep, which amounts fall within or overlap the claimed range of about 0.5-4.5 mg/kg diet dry matter. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to administer similar amounts of selenium to dogs or

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cats with the expectation that selenium administration would control the rate of hair growth or treat poor hair growth or alopecia in animals in which poor hair growth or alopecia is due to hypothyroidism that is caused by selenium deficiency and treatable by selenium supplementation and to use levels of selenium below 5 mg/kg diet dry matter in order to reduce the risk of selenium toxicity.

The Examiner has duly considered the Applicant's arguments but deems them unpersuasive.

The Applicant refers to the Specification at page 1, lines 19-26 and argues that the animals are not selenium deficient animals. However, the Specification at page 1, lines 19-26 does not state that the animals are not selenium deficient. Further, in the working example, the beagles tested were fed a basal diet that was deficient in selenium (Specification, paragraph 0012). In any case, the claims are not limited to animals that are not deficient in selenium. The limitation "properly nutritious diet" is not defined by the Specification. Since the only working example uses a diet which was deficient in selenium absent addition to the same to the diet, the limitation "properly nutritious diet" does not exclude diets that are deficient in selenium. The citation to page 3, paragraph 11 and 12 does not indicate that the dogs were not selenium deficient.

As indicated above, none of the amounts tested exhibited a rate of hair growth that was at least the same as that reported to be the average rate of hair growth for beagles. Since the Applicant's only example in the Specification failed to provide a rate of hair growth that at least meets the average rate of hair growth in beagles and does not provide evidence of new hair growth, said example fails to support the criticality of the claimed range for poor hair growth or

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alopecia in claims 3-5. With respect to claim 2, claim 2 only requires control of hair growth and thus is not limited to increasing the rate of hair growth but also encompasses reduction and maintenance of the rate of hair growth. As such, any amount in the prior art would "control" the rate of hair growth and the example fails to support the criticality of the claimed range. The Applicant argues that the working example showed an increase in growth rate, however, the example is not commensurate in scope with the claims. The claims have been amended to indicate that the dog or cat is receiving a properly nutritious diet. The Applicant seems to be arguing that this means that the diet already contains a sufficient amount of selenium. If this is the case, then the example is not representative of the claimed invention as the diet given in the example was deficient in selenium and had to be supplemented with selenium. The argument that the conditions in the Yu et al. reference cannot be compared with the conditions of the working example is not supported by evidence. The authors in Yu et al. are the applicants and as such would be in a position to know the comparative conditions between the working example and the conditions under which beagle hair growth was measured in the Yu et al. reference.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

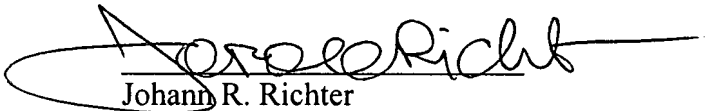
A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a compressed schedule and may be reached Monday, Tuesday, Thursday, Friday, 6:00 am – 4:30 pm (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Johann R. Richter, can be reached at (571)272-0646. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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November 9, 2007


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